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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PEPITONE, MICHAEL F

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,746	Applicant(s) BABA ET AL.	
	Examiner MICHAEL PEPITONE	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) in view of Shibata *et al.* (US 4,547,543). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claims 1-8, and 18: Baba *et al.* teaches an ocular lens material {contact lens [instant claim 18]} (1:5-12) comprising a polydimethylsiloxane compound having ethylenically unsaturated group bonded to the main chain with urethane bonds (2:60-4:45; 7:30-67), a pyrrolidone derivative {N-vinylpyrrolidone} (4:18; 9:58-63), wherein the pyrrolidone derivative is present in an amount of 7.5-40% [instant claim 2] (10:24-56; Tables 1 and 3 {col. 27-28}).

Baba *et al.* does not teach 1-methyl-3-methylene-2-pyrrolidone as the pyrrolidone derivative. However, Shibata *et al.* teaches a contact lens composition comprising 1-methyl-3-methylene-2-pyrrolidone [instant claims 3-4] (1:1-5; 1:54-62, 2:1-14), in conjunction with N-VP, and in an amount of 30 to 70 parts by weight of total hydrophilic monomers (2:46-61). Baba *et al.* and Shibata *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-3-methylene-2-pyrrolidone, as taught by Shibata *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Shibata *et al.* suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl groups, thereby decreasing poor optical and mechanical properties resulting from phase separation (1:40-62), as well as no substantial elution of a non-crosslinked N-MMP polymer is observed, and thus, the contact lens is highly safe for the eyes (4:63-5:3), and is an equivalent alternative means of providing a contact lens comprising pyrrolidone derivatives.

At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-5-methylene-2-pyrrolidone [instant claims 5-6], and 5-methyl-3-methylene-2-pyrrolidone [instant claims 7-8], which are regioisomers of 1-methyl-3-methylene-2-pyrrolidone. A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have

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similar properties.” In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979) [see MPEP 2144.09].

Regarding claim 9: Baba *et al.* teaches the repeating number of polydimethylsiloxane is 28 (7:28-45, compound A-1).

Regarding claim 10: Baba *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1].

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents. Therefore, the claimed effects and physical properties, i.e. a tensile modulus of 0.2 to 0.8 MPa, and a stress relaxation under loading a fixed load for 30 seconds is 8 to 15%, would inherently be achieved by a composition with all the claimed ingredients. If it is the applicants’ position that this would not be the case: (1) evidence would need to be presented to support applicant’s position; and (2) it would be the Office’s position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claims 11-12: Baba *et al.* teaches the water content is 29-50% by weight (Tables 4 and 6 {col. 29 and 30}).

Regarding claims 13-14: Baba *et al.* teaches tris(trimethylsiloxy)silylpropyl methacrylate (8:27-9:1).

Regarding claims 15-16: Baba *et al.* teaches N,N-dimethylacrylamide (10:11-18).

Regarding claim 17: Baba *et al.* at least one crosslinking agent (4:25-32).

Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) in view of Shibata *et al.* (US 4,547,543). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 19: Baba *et al.* teaches a method for preparing ocular lens material (1:5-12) comprising mixing a polydimethylsiloxane compound having ethylenically unsaturated group bonded to the main chain with urethane bonds (2:60-4:45; 7:30-67), a pyrrolidone derivative {N-vinylpyrrolidone}, and a photopolymerization initiator (20:63-21:16) or thermal polymerization initiator (19:47-20:8); the mixture was introduced to a mold; thermal or photo cured (22:40-23:25); a surface treatment procedure was employed to impart hydrophilic properties and lipid stain resistance (22:10-16); the residual monomers were extracted from the lens (25:17-45); the ocular lens material was hydrated (22:55-57).

Baba *et al.* does not teach 1-methyl-3-methylene-2-pyrrolidone as the pyrrolidone derivative. However, Shibata *et al.* teaches a contact lens composition comprising 1-methyl-3-methylene-2-pyrrolidone [instant claims 3-4] (1:1-5; 1:54-62, 2:1-14). Baba *et al.* and Shibata *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to incorporate 1-methyl-3-methylene-2-pyrrolidone into the polymer-forming system of Baba and one would have been motivated to do so since Shibata *et al.* suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl groups, thereby decreasing poor optical and mechanical properties resulting from phase separation (1:40-62) as well as no substantial elution of a non-crosslinked N-MMP polymer is observed, and thus,

the contact lens is highly safe for the eyes (4:63-5:3), and is an equivalent alternative means of providing a contact lens comprising pyrrolidone derivatives.

Regarding claim 20: Baba *et al.* teaches tris(trimethylsiloxy)silylpropyl methacrylate, and N,N-dimethylacrylamide (8:27-9:1; 10:11-18; 26:38-51; Tables 1-3).

Regarding claim 21: Baba *et al.* teaches a crosslinking agent (12:1-34; Tables 1 and 3 {col. 27-28}).

Regarding claim 22: Baba *et al.* teaches polymerizable UV absorbents and polymerizable dyes (16:66-17:3; 19:22-36).

Regarding claims 23-24: Baba *et al.* teaches 0.5 to 100 parts of a diluent {based on 100 parts monomer mixture}, specifically acetone (21:17-38).

Regarding claims 25-26: Baba *et al.* teaches the surface treatment procedure was a plasma treatment [instant claim 25] (22:10-16), and a plasma treatment with oxygen [instant claim 26] (22:10-16).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) in view of Shibata *et al.* (US 4,547,543), as applied to claim 26 above, and further in view of Valiant, JR. *et al.* (US 2002/0102415). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 27: Baba *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 26].

Baba *et al.* does not teach a plasma treatment with a mixture of oxygen and water [instant claim 27]. However, Valiant, JR. *et al.* teaches a method for surface treating contact lens

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material comprising a plasma treatment with a mixture of oxygen and water {air drawn through 5% hydrogen peroxide solution} [instant claim 27] (§ 10, 58). Baba *et al.* and Valiant, JR. *et al.* are analogous art because they are concerned with a similar technical difficulty, namely plasma treatment of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of oxygen and water, as taught by Valiant, JR. *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Valiant, JR. *et al.* suggests that such strong oxidizing plasma promote adhesion for bonding of the subsequent carbon deposition layer (§ 58), and is an equivalent alternative means of providing a plasma treatment for contact lenses.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) in view of Shibata *et al.* (US 4,547,543), as applied to claim 26 above, and further in view of Hayashi *et al.* (US 6,503,632). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 28: Baba *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 26].

Baba *et al.* does not teach a plasma treatment with a mixture of oxygen and tetrafluoromethane [instant claim 27]. However, Hayashi *et al.* teaches a method for surface treating contact lens material comprising a plasma treatment with a mixture of oxygen and tetrafluoromethane [instant claim 27] (1:10-18; 21:7-15). Baba *et al.* and Hayashi *et al.* are analogous art because they are concerned with a similar technical difficulty, namely plasma treatment of contact lenses. At the time of invention a person of ordinary skill in the art would

have found it obvious to have combined plasma treatments in the presence of oxygen and tetrafluoromethane, as taught by Hayashi *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Hayashi *et al.* suggests that such plasma treatment provide a substrate with substituents which a chemical reaction can proceed {the surface of the molded article may be chemically bonded further with a polymer or monomer} (21:16-23), and is an equivalent alternative means of providing a plasma treatment for contact lenses.

Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) in view of Shibata *et al.* (US 4,547,543), as applied to claim 26 above, and further in view of Walther *et al.* (US 6,379,004). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claims 29-30: Baba *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 26].

Baba *et al.* does not teach a plasma treatment with a mixture of oxygen and organic silane [instant claim 29], specifically tetramethoxysilane [instant claim 30]. However, Walther *et al.* teaches a method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and tetramethoxysilane [instant claims 29-30] (1:4-6; 10:48-62). Baba *et al.* and Walther *et al.* are analogous art because they are concerned with a similar technical difficulty, namely plasma treatment of ophthalmic lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of oxygen and tetramethoxysilane, as taught by Walther *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Walther *et al.* suggests that such plasma

treatment provide a substrate with both an interface layer and a grease protection layer (10:48-50), and is an equivalent alternative means of providing a plasma treatment for ophthalmic lenses.

Claims 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) in view of Shibata *et al.* (US 4,547,543), as applied to claim 26 above, and further in view of Turek *et al.* (US 2002/0137811). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claims 31-35: Baba *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 26].

Baba *et al.* does not teach a plasma treatment with a mixture of oxygen and methane [instant claim 31], and a mixture of oxygen, nitrogen, and methane [instant claim 32]. Baba *et al.* does not teach a surface treatment that is a coating method of a hydrophilic polymer coating [instant claim 33], specifically plasma polymerization of hydrophilic monomers [instant claim 34], and plasma-induced graft polymerizations [instant claim 35]. However, Turek *et al.* teaches a method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and methane [instant claim 31], and a mixture of air {oxygen and nitrogen} and methane [instant claim 32] (§105-110). Turek *et al.* also teaches a method for surface treating ophthalmic lens material comprising a plasma treatment coating method of a hydrophilic polymer coating [instant claim 33], specifically plasma polymerization of hydrophilic monomers [instant claim 34], and plasma-induced graft polymerizations [instant claim 35] (§105-110). Baba *et al.* and Turek *et al.* are analogous art because they are concerned with a similar technical

difficulty, namely the surface treating of ophthalmic lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of air and methane, and plasma induced polymerizations, as taught by Turek *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Turek *et al.* suggests that such plasma treatments provide a surface which is more ophthalmically compatible (§ 106), and is an equivalent alternative means of providing a surface treatment for ophthalmic lenses.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (WO 01/171415) in view of Shibata *et al.* (US 4,547,543), as applied to claim 19 above, and further in view of Niwa *et al.* (US 5,516,467). For the purpose of examination, Baba *et al.* (US 6,638,991) was used as the English translation of Baba *et al.* (WO 01/171415).

Regarding claim 36: Baba *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 19].

Baba *et al.* does not teach a method of coloring the ocular lens material by using a vat dye [instant claim 36]. However, Niwa *et al.* teaches a method for coloring contact lenses by using a vat dye [instant claim 36] (1:4-8; 2:26-49). Baba *et al.* and Niwa *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the coloring of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined vat dyes, as taught by Niwa *et al.* in the invention of Baba *et al.*, and would have been motivated to do so since Niwa *et al.* suggests that such vat dyes can be uniformly dispersed in the monomer mixture (2:64-3:10; 3:30-40), and is an equivalent alternative means of providing a method for coloring contact lenses.

Response to Arguments

Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

Baba *et al.* (US '991) discloses a contact lens material comprising a pyrrolidone derivative {N-vinylpyrrolidone, N-VP} (4:18; 9:58-63) and a polydimethylsiloxane compound having ethylenically unsaturated groups {(meth)acryloyl} bonded to the main chain with urethane bonds (7:25-8:2). Shibata *et al.* (US '543) clearly discloses N-methyl-3-methylene-2-pyrrolidone, N-MMP, to be used in conjunction with N-VP to improve the hardness and dimensional stability of the contact lens (2:46-56), as well as no substantial elution of a non-crosslinked N-MMP polymer is observed, and thus, the contact lens is highly safe for the eyes (4:63-5:3). N-MMP is to be used with N-VP, and not substituted for N-VP.

In response to applicant's arguments regarding Shibata *et al.* lack of suggestion that N-MMP would have a beneficial effect on systems (Baba *et al.*) using polysiloxane macromonomers, the disclosure of Shibata *et al.* clearly indicates N-MMP is highly copolymerizable with (meth)acryloyl moieties, resulting in a copolymer that is very well crosslinked and has little possibility of non-crosslinked N-MMP eluting. When N-MMP is used in combination with N-VP, the resulting contact lens material has superior transparency and optical properties (2:22-42). Whether or not a polysiloxane macromonomer is present is immaterial.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Shibata *et al.* (US '543) clearly discloses N-methyl-3-methylene-2-pyrrolidone, N-MMP, to be used in conjunction with N-VP to improve the hardness and dimensional stability of the contact lens (2:46-56), as well as no substantial elution of a non-crosslinked N-MMP polymer is observed, and thus, the contact lens is highly safe for the eyes (4:63-5:3).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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21-July-08

/Marc S. Zimmer/Primary Examiner, Art Unit 1796

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